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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,680	06/07/2001	Wade Blair	3053-4087	8187

7590 11/28/2003

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/28/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/876,680	Applicant(s) BLAIR ET AL.	
	Examiner Myron G. Hill	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 25 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

This action is in response to Amendment A, paper 9.

Claims 1- 23 are pending.

Information Disclosure Statement

A signed and initialed copy of IDS paper #7, filed January 27, 2003, is enclosed.

Rejections Withdrawn

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4, 10, and 11 were rejected under 35 U.S.C. 102(b) as being anticipated by Haseltine.

Claim 1 was amended to include the limitation "suitable for use in a high volume anti-viral assay" Claims 2, 4, 10, and 11 depend from claim 1.

The claims are drawn to a vector that encodes a replication competent HIV-1 virus, the vector comprising a deletion in a non-essential region and a reporter gene inserted and the vector is suitable for use in a high volume anti-viral assay.

Applicant argues that the prior art vectors, such as the one used on page 17 of the application, do not produce reporter gene after the third day of infection and this

does not allow for late stage inhibitors of viral replication. Applicant additionally states, Haseltine uses a CAT reporter gene and that a CAT reporter gene is not suitable for a high volume anti-viral screening assay.

Applicant's arguments have been fully considered and found persuasive in part.

The limitation added in the amendment, that the "vector is suitable for use in a high volume anti-viral assay" is considered to be a critical limitation that requires the use of a reporter gene that can be measured by rapid and simple assays. CAT assays are cumbersome and have a limited activity range (paragraph spanning pages 2 and 3 of the specification). The use of the CAT reporter in high throughput assays at the time of invention was not common. Grentzmann et al. (RNA 1998 Vol 4, No. 4, pages 479- 486, abstract only) is cited as evidence that renilla and firefly luciferase are in use as reporter genes for use *in vitro* and *in vivo* assays which are also applicable for high throughput assays.

The arguments concerning duration of reporter gene activity and late stage activity are not commensurate with the scope of the claims; however, they are moot in light of the new claim limitation.

Modified Rejections

Claim Rejections - 35 USC § 103

Claims 1- 4, 10, 11, 13- 15, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haseltine and Liu et al.

This rejection has been modified to include claims 1, 2, 4, 10, and 11 that were part of the withdrawn 102(b) rejection and are included because of the amendment to claim 1.

The claims are drawn to a vector that encodes a replication competent HIV-1 virus, the vector comprising a deletion in a non-essential region and a reporter gene inserted and the vector is suitable for use in a high volume anti-viral assay.

Applicant argues that Examiner does not set forth motivation to combine Liu with Haseltine.

Applicant's arguments have been fully considered and not found persuasive.

One of ordinary skill in the art at the time of invention would have been familiar with the requirements for doing a "CAT assay" (preparing a lysate, incubating the sample in reaction mix, extracting the sample, drying the sample, resuspending the sample, running it out on TLC plates, and waiting for the film to develop) and Haseltine teaches that a reporter gene is needed. Liu et al. teach that secreted reporter proteins offer the advantage of permitting monitoring over time and light-emitting reporter gene assays are particularly convenient because their assays offer great sensitivity and permit easy quantitation of the reporter gene (paragraph 1, page 153). Liu et al. teaches an improved luciferase (page 154, top of column 1). One of ordinary skill in that at the time of invention would know that high throughput assays require steps that can be automated or carried out with large numbers of samples. Grentzmann et al., cited above, teaches that renilla luciferase is suitable for high throughput assays. One of ordinary skill in the art at the time of invention would have been motivated to replace the

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CAT reporter gene of Haseltine with a secreted reporter gene as taught by Liu et al. because the infected cells could be monitored over time, the ease of quantitation of reporter gene, and higher level of sensitivity that is possible with the reporter genes of Liu et al. as compared to the CAT reporter gene of Haseltine.

Thus, it would have been *prima facie* obvious to replace the reporter gene of Haseltine with the reporter gene of Liu et al. to make a vector that is suitable for high throughput screening with the expectation of success.

Claims 5, 6, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haseltine and Liu et al., as applied to claims 1- 4, 10, 11, 13- 15, 21, and 22 above, and Gibbs.

Applicant argues that Haseltine sets forth a vector that is not suitable for high throughput screening assays and the Gibbs does not remedy the deficiencies of Haseltine.

Applicant's arguments have been fully considered and not found persuasive.

As discussed above, Haseltine and Liu et al. meet the limitations of claim 1.

Claims 9- 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haseltine and Liu et al., as applied to claims 1- 4, 10, 11, 13- 15, 21, and 22 above, and Shi et al.

Applicant argues that Haseltine sets forth a vector that is not suitable for high throughput screening assays and the Shi does not remedy the deficiencies of Haseltine.

Applicant's arguments have been fully considered and not found persuasive.

As discussed above, Haseltine and Liu et al. meet the limitations of claim 1.

Claims 7, 8, 18- 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haseltine and Liu et al., as applied to claims 1- 4, 10, 11, 13- 15, 21, and 22 above, and Collman or Li or Shi.

Applicant argues that Haseltine sets forth a vector that is not suitable for high throughput screening assays and that none of Collman or Li or Shi remedy the deficiencies of Haseltine.

Applicant's arguments have been fully considered and not found persuasive.

As discussed above, Haseltine and Liu et al. meet the limitations of claim 1.

Conclusion

The limitation added by amendment necessitated the change of the 102 rejection to a 103. The 103 rejections of record are modified to include this change.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

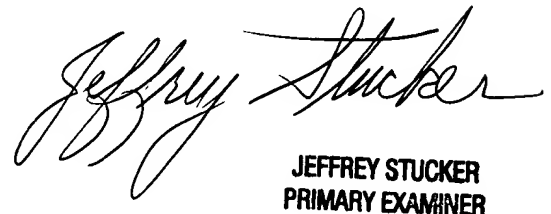
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Myron G. Hill

Patent Examiner

November 19, 2003



JEFFREY STUCKER
PRIMARY EXAMINER